

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C. A. No. 06-222 (JJF)
	)	
IMPAX LABORATORIES, INC.,	)	
	)	
Defendant.	)	
	)	

**WYETH'S OPENING BRIEF IN SUPPORT OF ITS  
MOTION TO STRIKE PARAGRAPHS 72-73, 81-84, 129-130 AND  
133-136 OF THE REBUTTAL EXPERT REPORT OF ARTHUR H. KIBBE, Ph.D.**

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### NATURE AND STAGE OF PROCEEDINGS

On October 31, 2007, Impax Laboratories, Inc. ("Impax") served a third expert report of Dr. Kibbe, entitled "Rebuttal Expert Report of Arthur H. Kibbe, Ph.D."<sup>1</sup> Wyeth has moved to strike paragraphs 72-73, 81-84, 129-130 and 133-136 of Dr. Kibbe's Rebuttal Expert Report because they raise new and untimely invalidity defenses and claim construction positions. Pursuant to the Court's Scheduling Order, claim construction briefing was completed in May, 2007, and the Court has already conducted a Markman hearing. (D.I. 27 at ¶ 8). In addition, Impax was required to submit all expert opinions on issues for which it has the burden of proof, including invalidity, by September 28, 2007. (*Id.* at ¶ 3(e)). The Scheduling Order also permitted rebuttal expert reports, served October 31, 2007, to address opinions set forth by the other side's experts. (*Id.*). Impax's rebuttal expert reports therefore should have solely addressed infringement issues, for which Wyeth bears the burden of proof. Several portions of Dr. Kibbe's report, however, contain new invalidity opinions. In essence, Impax seeks to use the "rebuttal" report to belatedly supplement Dr. Kibbe's opening report on invalidity.

This is Wyeth's opening brief in support of its motion to strike this untimely and unauthorized supplementation.

### SUMMARY OF ARGUMENT

Dr. Kibbe's Rebuttal Expert Report includes new indefiniteness opinions and raises new claim construction positions that are contrary to constructions to which Impax had earlier agreed. These new opinions should be stricken because Impax did not timely raise these issues and Wyeth is unfairly prejudiced, because it lacks a fair and full opportunity to formulate

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<sup>1</sup> Impax previously served an opening expert report of Dr. Kibbe on September 28, 2007 and a supplemental report (without leave of court) on October 20, 2007.

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a proper response at this late stage in the litigation. Claim construction briefs were filed months ago, the Court has already held a *Markman* hearing, and the parties are preparing for expert depositions. Case dispositive motions are due on November 30, 2007 and the Court has set a pretrial conference for January 10, 2008. It would be unduly prejudicial to Wyeth to have to respond to new invalidity and claim construction positions, for which it had no prior notice – particularly on claim constructions to which Impax agreed.

### STATEMENT OF FACTS

#### A. Dr. Kibbe's New Opinions On Indefiniteness

In his Rebuttal Expert Report, Dr. Kibbe asserts for the first time that the phrase “provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml” as it appears in the asserted claims of the ‘120 patent is indefinite. (Declaration of Karen Jacobs Loudon (“Louden Decl.”) Ex. A, ¶¶ 84, 133). Dr. Kibbe contends that this claim language, with respect to the 150 ng/ml peak, “is not associated with any dosage of the extended release formulation of venlafaxine,” nor “associated with patient size.” (*Id.* at ¶ 134). He opines that, without this information, “there is no meaningful context for the claimed  $C_{\max}$  or peak blood plasma level,” and that “[a] person of ordinary skill in the art reading the claim would not know under what circumstances the claimed formulation would achieve the claimed  $C_{\max}$ .” (*Id.*; see also *id.* at ¶¶ 135-36). Significantly, Dr. Kibbe does not use his new “construction” of this phrase to contest Impax’s infringement; rather he uses it to belatedly challenge the validity of the patents.

Dr. Kibbe did not include this new indefiniteness argument in his opening expert report, even though the Court’s July 13, 2006 Scheduling Order specifically required the parties to serve expert reports on the issues for which it bears the burden of proof by September 28, 2007. (D.I. 27 at ¶ 3(e)). This is not Dr. Kibbe’s first untimely, unauthorized report. Impax

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served a “Supplemental” expert report for Dr. Kibbe three weeks after the deadline for opening expert reports, purportedly relying on “new” evidence to support additional opinions. Yet Dr. Kibbe still failed to include this new indefiniteness argument in his supplemental expert report. Moreover, Dr. Kibbe does not point to anything in Wyeth’s opening expert reports that would justify raising his new argument in rebuttal. Nor could he. Any arguments about the purported indefiniteness of the claim language was equally available to Impax from the start of the case.<sup>2</sup>

Dr. Kibbe also opines that the claim language “therapeutic metabolism” is indefinite. (*Id.* at ¶ 81). He contends that, although the terms “therapeutic” and “metabolism” have plain meanings to a skilled artisan, “therapeutic metabolism” does not. (*Id.*). He thus concludes that “the claim term is meaningless and indefinite to a person of ordinary skill in the art.” (*Id.*). Here again, Dr. Kibbe could have, but inexplicably failed to, include this argument in his opening expert report concerning validity. Because of its failure to abide by the Scheduling Order, Impax deprived Wyeth of the ability to address this issue in its rebuttal expert reports.

Plainly any indefiniteness issues as to claim language could have, and should have, been raised long ago.

B. Dr. Kibbe’s New Claim Construction Opinions.

Pursuant to the Court’s July 13, 2006 Scheduling Order, the parties exchanged their proposed claim constructions on April 13, 2007. (D.I. 27, ¶ 8; Louden Decl., Exs. E and F). In correspondence dated April 23 and 24 2007, the parties proposed that they adopt Wyeth’s construction of “encapsulated” and Impax’s construction of “spheroid” as agreed-upon

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<sup>2</sup> Despite amending its responses to Wyeth’s contention interrogatories twice, on October 10, 2006 and January 12, 2007, Impax has never asserted that the 150 ng/ml peak claim language was indefinite. See Impax’s Original, First Amended and Second Amended Response to Interrogatory No. 2. (Louden Decl., Exs. B, C and D).

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constructions.<sup>3</sup> (Louden Decl., Ex. E, F and G). The parties held a meet and confer session on April 25, 2007 and confirmed the agreements reached during that telephone conference in an April 26, 2007 letter. (Louden Decl., Ex. H). Specifically, the parties agreed that the only claim terms remaining in dispute were:

1. “with diminished incidence[s] of nausea and emesis”;
2. “extended release formulation”; and,
3. “A method for eliminating the troughs and peaks of drug concentration in a patient’s blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride.”

(*Id.*). They further confirmed their agreement on the construction of the claim term “spheroid” (adopting Impax’s proposed construction) and “encapsulated” (adopting Wyeth’s proposed construction). (*Id.*).

Claim construction briefing proceeded on the three disputed claim terms. The parties filed opening claim construction briefs on May 8, 2007 and answering briefs on May 25, 2007. The Court held a *Markman* hearing on June 12, 2007.

Nevertheless, Dr. Kibbe raised a number of new claim construction issues in his Rebuttal Expert Report. Most notably, Dr. Kibbe proffers constructions of “spheroid” and “encapsulated” that are at odds with the definitions to which the parties agreed. (Louden Decl., Ex. A at ¶¶ 72-73). For example, Dr. Kibbe now tries to add a limitation that the spheroid must be “uncoated” (*Id.* at ¶ 72). He further asserts that “encapsulated” can also mean “to surround with a coating.” (*Id.* at ¶ 73).

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<sup>3</sup> Wyeth proposed that “encapsulated” be construed to mean “filled into a pharmaceutically acceptable carrier.” (Louden Decl., Ex. E). Impax proposed that “spheroid” be construed to mean “one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round.” (Louden Decl., Ex. F).

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Finally, with respect to the claim language “a peak blood plasma level of venlafaxine in from about 4 to 8 hours (or about 5 to 8 hours, or about 6 hours),” Dr. Kibbe opines that “[a] person of ordinary skill in the art would understand that ‘about’ means that the variance from the specific range would be *statistically insignificant*.” (*Id.* at ¶ 82) (emphasis added). He further opines that “[s]tatistically significant differences would be outside the scope of the claims.” (*Id.*). Again, Dr. Kibbe does not use his construction of “about” to contest Impax’s infringement; rather he uses his construction to belatedly challenge the validity of the patents. Thus, based on his interpretation of “about” as meaning “not statistically significantly different,” Dr. Kibbe argues that “the formulation of extended release venlafaxine disclosed in the Alza ‘457 patent, and used in the 134 study, fall within the range of asserted claims of the patents-in-suit containing this limitation.” (*Id.* at ¶ 83; *see also id.* at ¶¶ 129-30).

#### ARGUMENT

Dr. Kibbe’s new claim construction and indefiniteness opinions should be stricken because they are untimely under the Court’s July 13, 2006 Scheduling Order (D.I. 27), are without substantial justification, and prejudice Wyeth.

Courts in this District routinely preclude parties from relying on contentions that were not properly disclosed during discovery. *See, e.g., Bridgestone Sports Co., Ltd. v. Acushnet Co.*, 2007 U.S. Dist. LEXIS 11370 (D. Del. Feb. 15, 2007) (precluding Acushnet from relying on prior art references that were not timely disclosed); *Praxair, Inc. v. ATMI, Inc.*, 2005 WL 3159054 (D. Del. Nov. 28, 2005) (precluding defendant from relying on undisclosed prior art references and striking portions of defendants’ expert reports); *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 1996 U.S. Dist. LEXIS 22616, \*33-35 (D. Del. Dec. 27, 1996) (precluding defendants from advancing certain invalidity defenses for failure to comply with set deadlines for discovery); *Matsushita Electric Indus. Co., Ltd. v. Cinram Int’l, Inc.*, 229 F. Supp. 2d 348,



366 (D. Del. 2004) (striking defendant's non-infringement theory advanced late in the proceedings); *The Liposome Co. v. Vestar, Inc.*, C.A. No. 92-332-RRM (D. Del. Nov. 24, 1993) ("As Liposome failed to identify this contention [regarding infringement under the doctrine of equivalents] in response to Vestar's discovery request, the Court will preclude it from relying on it at trial.") (Louden Decl., Ex. I).

In considering whether to exclude testimony, the Third Circuit has identified the following relevant factors and circumstances: (1) the prejudice or surprise to a party against whom the evidence is offered; (2) the ability of the injured party to cure the prejudice; (3) the likelihood of disruption to the trial schedule; (4) bad faith or willfulness involved in not complying with the disclosure rules; and (5) the importance of the evidence to the party disclosing it. *Bridgestone*, 2007 U.S. Dist. LEXIS 11370, at \*10-11 (citing *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1997)).

As this court acknowledged in *Bridgestone*, "[c]ourts applying the *Pennypack* factors in the case of sophisticated, complex litigation involving parties represented by competent counsel have been less indulgent in their application and more willing to exclude evidence without a strict showing that each of the *Pennypack* factors has been satisfied." *Id.* at \*11 (citing *AstraZeneca AB v. Mutual Pharm. Co.*, 278 F. Supp. 2d 491 (E.D. Pa. 2003)). The Court's observations in *Bridgestone* are in many ways applicable here:

As the Court has discussed, the parties to this litigation are sophisticated business entities, leaders in their field, who are represented by counsel well-versed in complex patent litigation. Numerous and contentious discovery disputes have been brought to the Court by both parties . . . Considering these circumstances, as well as the nature of the evidence sought to be precluded, the Court has concluded that Acushnet should be precluded from relying on its untimely disclosed prior art references.

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The parties here likewise are sophisticated business entities, represented by competent counsel, who have engaged in extensive discovery and have had a number of discovery disputes.

There is no justification for Impax's late disclosure of its new theories. Claim construction briefing closed on May 25, 2007 and the Court already has held a *Markman* hearing. Impax does not even attempt to justify why it is entitled to raise new claim construction issues that were not briefed or argued to the Court. Nor does it explain why it should be permitted to modify the constructions of two claim terms ("spheroid" and "encapsulated") as to which it *specifically agreed*. Impax also could have raised its indefiniteness arguments in a timely fashion. Impax does not even attempt to justify its failure to raise its new indefiniteness contentions in Dr. Kibbe's opening expert report, which was required to include all of his opinions on issues for which Impax bears the burden of proof. (D.I. 27, ¶ 8).

Wyeth would be prejudiced by the late introduction of these new theories. Claim construction briefing is closed. Expert reports have been served and expert discovery is underway. Case dispositive motions are due on November 30, 2007 and a pretrial conference has been set for January 10, 2008. As this Court has held, "[i]n every trial there comes a time when discovery must be closed for issues to be resolved through summary judgment and/or trial." *Stambler v. RSA Sec., Inc.*, 21 F.R.D. 470, 472 (D. Del. 2003).

Dr. Kibbe's new opinions would now require Wyeth to formulate a response and submit further expert reports after the deadline for the service of rebuttal reports, at the same time that Wyeth is preparing for expert depositions. Impax's *ad hoc* disclosure of expert opinions on a rolling basis is clearly improper. Wyeth is already burdened with having to respond to Dr. Kibbe's unauthorized supplemental report, to which it did not object in the spirit of cooperation. Allowing Impax to include untimely opinions on validity in Dr. Kibbe's rebuttal

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expert report would further, and unjustifiably, add to Wyeth's burden. This Court precluded Acushnet from relying on additional prior art references in *Bridgestone*, even though the additional time required to respond would be moderate, because "the additional time and expense that would follow are consequences which could have been avoided." *Bridgestone*, 2007 U.S. Dist. LEXIS at \*15; *see also AMEX, LLC v. Mopex, Inc.*, 215 F.R.D. 87 (S.D.N.Y. 2002) (granting motion to preclude plaintiff from supplementing its interrogatory answers to allege infringement of an additional patent claim after the close of fact discovery and just before exchange of expert reports where there was no justification for the delay and defendant was prejudiced because additional fact discovery would be required that would necessitate delays); *Philips Elecs. N. Am. Corp. v. Contec Corp.*, 2004 U.S. Dist. LEXIS 5839, at \*5 (D. Del. Apr. 5, 2004) (precluding party from using untimely produced documents at trial where there was no reasonable excuse for the delay and acknowledging that "an 'A' for effort [in complying with Rule 37] does not excuse [a party's] failure to abide by its disclosure obligations"); *AstraZeneca AB v. Mutual Pharm. Co.*, 278 F. Supp. 491, 508 (E.D. Pa. 2003) (excluding defendant's reliance on prior art patent where ensuing delay would not disrupt the trial date and no bad faith was shown, but defendant offered no excuse sufficient to ignore the Court's scheduling deadlines); *Georgia-Pacific Corp.*, 1996 U.S. Dist. LEXIS 22616, at \*33-35 (precluding defendants from advancing certain invalidity defenses because they failed to comply with discovery deadlines).

Dr. Kibbe's untimely opinions here likewise should be excluded.

#### CONCLUSION

For the foregoing reasons, Wyeth respectfully requests that its motion to strike paragraphs 72-73, 81-84, 129-130 and 133-136 of the Rebuttal Expert Report of Arthur H. Kibbe, Ph.D. be granted.

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on November 15, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer  
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I also certify that copies were caused to be served on November 15, 2007 upon the following in the manner indicated:

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